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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES AND RAMESH "SUNNY" BALWANI, Defendants.	Case No. CR 18-00258-EJD STIPULATION AND ~~[PROPOSED]~~ ORDER REGARDING CERTAIN FDA DOCUMENTS

STIPULATION

WHEREAS, on April 15, 2019, defendant Elizabeth Holmes moved to compel federal prosecutors (the "Prosecution") to produce six categories of documents in the possession of the U. S. Food and Drug Administration ("FDA") and Centers for Medicare & Medicaid Services ("CMS") (together, the "Agencies"). Defendant Ramesh Balwani joined that motion on April 16, 2019.

WHEREAS, on November 5, 2019, the Court issued an Order Granting Motion to Compel production of documents held by FDA and CMS responsive to the following categories:

1. Any and all correspondence or communications regarding Theranos between the government and John Carreyrou, *The Wall Street Journal*, or their employees, agents, or counsel,

and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;

2. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;

3. Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or interagency correspondence) regarding same;

4. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;

5. Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and

6. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

WHEREAS, the Court found "the Prosecution has knowledge of and access to the at-issue documents" and "order[ed] the Prosecution to produce the documents discussed below as part of their Rule 16 obligation, and to assist the Agencies however possible to ensure the timely production of documents." ECF No. 174 at 3.

WHEREAS, the Court also ordered "that FDA shall run searches of all of its custodians' documents using the following terms: "LDT," "Laboratory Developed Test," "Theranos," "fingerstick" or "finger stick," and "nanotainer" . . . [and] shall produce any responsive documents returned by these searches." ECF No. 174 at 3.

WHEREAS, following a meet and confer session on November 8, 2019, counsel for the defense suggested the terms "Laboratory-Developed Test," or "Lab-developed test," or "finger stick," or "finger-stick," or "Holmes" also be run, in addition to the following terms that the FDA advised on October 4, 2019, had been run for certain custodians: Balwani OR "Elizabeth w/3 Holmes" OR eholmes OR eholmes2003 OR eholmes@theranos.com OR Theranos OR "TSPU" OR "TSCD" OR Nanotainer OR "Capillary Tubes" OR "Nanotainer Tubes" OR "Lithium-Heparin" OR "CTN" OR "K2EDTA" OR "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR "Q160470" OR "K143236" OR "CW150009" OR "TLAS."

WHEREAS, Title 21 U.S.C. § 331(j) prohibits "revealing, other than to the Secretary [of Health and Human Services] or officers or employees of the Department [of Health and Human Services], or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of [certain sections of the Federal Food, Drug, and Cosmetic Act ("FDCA")] concerning any method or process which as a trade secret is entitled to protection."

WHEREAS, Title 21 U.S.C. § 360j(c), relating to trade secrets and confidential commercial information, provides: "[a]ny information reported to or otherwise obtained by the Secretary or his representative under [certain medical device and inspectional sections of the FDCA] which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed."

WHEREAS, to facilitate compliance with the Order, the FDA is preparing to produce to the Department of Justice ("DOJ") documents collected from its custodians using each of the search terms described above ("Ordered FDA Documents") without further review for trade secret, confidential commercial information, or privileged information, but believes it cannot lawfully do so absent an order of this Court.

WHEREAS, no party objects to entry of a further order directing the FDA to produce the Ordered FDA Documents to DOJ for the purpose of producing the above-described categories of documents. Defendants agree that production by the FDA to DOJ shall not constitute a waiver of any applicable privilege.

THEREFORE, the parties stipulate and agree, and respectfully request the Court issue the proposed order below, ordering the FDA to produce the Ordered FDA Documents to DOJ notwithstanding the provisions of 21 U.S.C. §§ 331(j) and 360j(c). The parties further note that they will jointly move to amend or supplement the protective orders in this case to address the appropriate handling and review of the FDA documents that will be produced by DOJ to Defendants in this case.

IT IS SO STIPULATED.

DATED: December 1, 2019

ADAM A. REEVES
Attorney for the United States,
Acting Under Authority Conferred By
28 U.S.C. § 515

/s/
_____
ROBERT S. LEACH
Assistant United States Attorney

DATED: December 1, 2019

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DATED: December 1, 2019

ORRICK HERRINGTON & SUTCLIFFE, LLP

/s/
_____
JEFFREY B. COOPERSMITH
Attorneys for Defendant Ramesh Balwani

~~[PROPOSED]~~ ORDER

Based upon the facts set forth in the stipulation of the parties and for good cause shown, the Court hereby ORDERS the FDA to produce the Ordered FDA Documents to DOJ notwithstanding the provisions of 21 U.S.C. §§ 331(j) and 360j(c) for the purpose of producing to the defense documents responsive to the six categories identified in the Court's November 5, 2019 Order (Dkt. No. 174).

IT IS SO ORDERED.

DATED: 12/2/2019

THE HONORABLE EDWARD J. DAVILA
United States District Judge